



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

May 23, 2011

MEMORANDUM

Subject: Efficacy Review for PERACLEAN ® 15; EPA Reg. No. 54289-4; DP Barcode: D387212

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Ph.D.
Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell / Martha Terry
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Evonik Degussa Corporation
379 Interpace Parkway
Parsippany, NJ 07054-0677

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
Hydrogen Peroxide	22.0 %
Peroxyacetic Acid	15.0 %
<u>Other ingredients</u>	<u>63.0 %</u>
Total.....	100.0 %

I. BACKGROUND

The product, PERACLEAN ® 15 (EPA Reg. No. 54289-4), is an EPA-approved disinfectant (bactericide, fungicide) and sanitizer for use on hard, non-porous surfaces in commercial, institutional, industrial, food preparation, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as an antimicrobial rinse in reducing the number of non-pathogenic beverage spoiling organisms, including *Aspergillus versicolor*, *Byssoschlamys fulva*, *Lactobacillus buchneri*, *Pediococcus damnosus*, and *Saccharomyces cerevisiae*. The label states that the product is effective as a sanitizer in water of up to 400 ppm hardness as CaCO₃. Studies were conducted at MICROBIOTEST, located at 105B Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to EPA (dated January 5, 2011), two studies (MRID 483605-01 and 483605-02), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, PERACLEAN 5 (EPA Reg. No. 54289-3). The applicant's letter to EPA (dated January 5, 2011) states that the tested product, PERACLEAN 5, is almost identical – when prepared according to label instructions – to the product, PERACLEAN ® 15, which is the subject of this efficacy report.

II. USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces, including: equipment, pipelines, tanks, vats, fillers, evaporators, and pasteurizers. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: aluminum, baked enamel, chrome, glass, glazed ceramic, glazed porcelain, glazed tile, laminated surfaces, linoleum, painted surfaces, plastic (e.g., polyethylene, polypropylene), sealed stone, stainless steel, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product as an antimicrobial rinse in reducing the number of non-pathogenic beverage spoilage organisms: Pre-clean containers. Prepare a use solution by adding 9.85 ounces of the product and 5 gallons of water (a 1:65 dilution). Apply use solution (antimicrobial rinse) at a temperature of 40-60°C and allow a minimum 7-second contact time. Allow containers to dry thoroughly. Rinse with sterile or potable water.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria):

There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. EPA staff indicated that the DIS/TSS-5 standards are silent on this matter and that confirmatory test standards would apply. EPA staff indicated that, for sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and 125 x 10⁶/mL for percent reductions to be

considered valid. Label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization.

Supplemental Claims: On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 483605-01 “Germicidal and Detergent Sanitizing Action of Disinfectants,”
Test Organisms: *Aspergillus versicolor* (ATCC 9577) and *Byssoschlamys fulva* (ATCC 10099), for PERACLEAN 5, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – July 13, 2004. Laboratory Project Identification Number 529-102.

This study was conducted against *Aspergillus versicolor* (ATCC 9577) and *Byssoschlamys fulva* (ATCC 10099). Two lots (Lot Nos. 1110003 and 2101003) of the product, PERACLEAN 5, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. Use solutions were prepared by adding 4.72 or 4.80 mL of the product and 99 mL of 400±2.9% ppm AOAC synthetic hard water (a ~1:22 dilution; 2,632 ppm peroxyacetic acid). Use solutions were not tested in the presence of a 5% organic soil load. Two replicates per product lot were tested. A 99-mL aliquot of each use solution was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 40°C. One-mL fungi suspension was added to each flask. One-mL aliquots of the fungi-product mixture were transferred to tubes containing D/E Neutralizing Broth exactly 7 seconds after the addition of the fungi suspension. Neutralizer tubes were mixed thoroughly and serially diluted in phosphate buffer dilution water. Selected aliquots were plated in Czapek agar (for *Byssoschlamys fulva*) or Potato Dextrose agar (for *Aspergillus versicolor*). All plates were incubated for 3-5 days at 25-30°C. Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness, and confirmation of the challenge microorganisms.

Note: Protocol deviations/amendments reported in the study were observed.

2. MRID 483605-02 “Germicidal and Detergent Sanitizing Action of Disinfectants,”
Test Organisms: *Lactobacillus buchneri* (ATCC 4005), *Pediococcus damnosus* (ATCC 29358), and *Saccharomyces cerevisiae* (ATCC 47058), for PERACLEAN 5, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – July 13, 2004. Laboratory Project Identification Number 529-103.

This study was conducted against *Lactobacillus buchneri* (ATCC 4005), *Pediococcus damnosus* (ATCC 29358), and *Saccharomyces cerevisiae* (ATCC 47058). Two lots (Lot Nos. 1110003 and 2101003) of the product, PERACLEAN 5, were tested. The laboratory report referenced the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. In studies against *Lactobacillus buchneri* and *Pediococcus damnosus*, use solutions were prepared by adding 1.10 or 1.11 mL of the product and 99 mL of 400±2.9% ppm AOAC synthetic hard water (a 1:90 to 1:91 dilution; 643 ppm peroxyacetic acid). In studies against *Saccharomyces cerevisiae*, use solutions were prepared by adding 4.72 or 4.80 mL of the product and 99 mL of 400±2.9% ppm

AOAC synthetic hard water (a ~1:22 dilution; 2,632 ppm peroxyacetic acid). Use solutions were not tested in the presence of a 5% organic soil load. Two replicates per product lot were tested. A 99-mL aliquot of each use solution was transferred to a 250 mL Erlenmeyer flask and placed in a water bath at 42°C. One-mL inoculum suspension was added to each flask. One-mL aliquots of the inoculum-product mixture were transferred to tubes containing D/E Neutralizing Broth exactly 7 seconds after the addition of the inoculum suspension. Neutralizer tubes were mixed thoroughly and serially diluted in phosphate buffer dilution water. Selected aliquots were plated in Reinforced Clostridial Medium Agar (for *Lactobacillus buchneri* and *Pediococcus damnosus*) or YM agar (*Saccharomyces cerevisiae*). All plates were incubated for 4 days at 37±2°C (25-26°C for *Pediococcus damnosus* and *Saccharomyces cerevisiae*). Following incubation, the colonies were counted. Controls included those for numbers count, sterility, neutralizer effectiveness, and confirmation of the challenge microorganisms.

Note: Protocol deviations/amendments reported in the study were observed.

V. RESULTS

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/carrier)		
7-Second Exposure Time					
483605-01	<i>Aspergillus versicolor</i>	1110003	2.5 x 10 ¹ †	9.6 x 10 ⁷	>99.999
		2101003	2.0 x 10 ¹	9.6 x 10 ⁷	>99.999
	<i>Byssoschlamys fulva</i>	1110003	3.6 x 10 ² †	8.1 x 10 ⁷	>99.999
		2101003	3.4 x 10 ² †	8.1 x 10 ⁷	>99.999
483605-02	<i>Lactobacillus buchneri</i>	1110003	<5.0 x 10 ⁰	9.4 x 10 ⁷	>99.999
		2101003	<5.0 x 10 ⁰	9.4 x 10 ⁷	>99.999
	<i>Pediococcus damnosus</i>	1110003	<5.0 x 10 ⁰	8.0 x 10 ⁷	>99.999
		2101003	<5.0 x 10 ⁰	8.0 x 10 ⁷	>99.999
	<i>Saccharomyces cerevisiae</i>	1110003	<5.0 x 10 ⁰	8.2 x 10 ⁷	>99.999
		2101003	<5.0 x 10 ⁰	8.2 x 10 ⁷	>99.999

†Maximum of two replicates reported.

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of a ~1:22 dilution of the product, PERACLEAN 5, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 7-second contact time at 40-42°C:

Aspergillus versicolor
Byssoschlamys fulva
Saccharomyces cerevisiae

MRID 483605-01
MRID 483605-01
MRID 483605-02

Fungi/yeast reductions of at least 99.999 percent over the parallel control were observed within 30 seconds (actual time: 7 seconds). Neutralizer effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of a 1:90 to 1:91 dilution of the product, PERACLEAN 5, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 7-second contact time at 42°C:

Lactobacillus buchneri
Pediococcus damnosus

MRID 483605-02
MRID 483605-02

Bacteria reductions of at least 99.999 percent over the parallel control were observed within 30 seconds (actual time: 7 seconds). Neutralizer effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

VII. LABEL

1. The proposed label claims that a 1:65 dilution (2,632 ppm peroxyacetic acid) of the product, PERACLEAN ® 15, is an effective antimicrobial rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces in the presence of 400 ppm hard water for a 7-second contact time at 40-42°C:

Aspergillus versicolor
Byssoschlamys fulva
Lactobacillus buchneri
Pediococcus damnosus
Saccharomyces cerevisiae

These claims are acceptable as they are supported by the submitted data.

2. The applicant must make the following changes to the proposed label, as appropriate:

- Under the "Precautionary Statements" section of the proposed label, change "before eating, drinking, using tobacco, or using the toilet" to read "before eating, drinking, **chewing gum**, using tobacco, or using the toilet."
- Add ATCC numbers for all listed microorganisms.